

REMARKS

Entry of the amendments is respectfully requested. Claims 19, 20, 21, 22, 24, 30-32, and 35 have been have been amended. New claims 40-44 have been added. Claims 1-44 are pending in the application. Favorable reconsideration and allowance of this application is respectfully requested in light of the foregoing amendments and the remarks that follow.

1. **Rejection Under §101**

Claims 19-22, 25, 27-29 stand rejected under 35 U.S.C. §101. Claim 19 has been amended per the Examiner's suggestion for purposes of clarity and not to alter the scope of any claims. The remaining claims depend from claim 19. Therefore, withdrawal of this rejection is requested.

2. **Rejection Under §112, Second Paragraph**

Claims 19-35 stand rejected under 35 U.S.C. §112, ¶2 as being indefinite.

Claim 19 is rejected due to the reference to Figure 1. The Examiner asserts the following on Page 3 of the Office Action.

the genus of *Lactobacillus* strains intended to be encompassed by this terminology cannot be readily assessed. There is no clear indication as to how many Profile I there are and whether there are other means of obtaining or reaching this designation. In addition, the Figure is not clearly legible. Thus, the results depicted therein cannot be interpreted or ascertained. Table 6 provides strain designations and species designations, but the correlation with Profile I is unclear. The Figure and Table are not informative regarding the specific properties of the strains intended to be claimed. The reasons or criteria for designating pigs as "representative" for inclusion in Table 6 data are not set forth with any particularity on the record.

The specific issues listed above will be addressed in the order they were raised. First, as it is currently understood, when digesting genomic DNA of strains of *Lactobacillus* with *Apa* I, *Not* I and *Xba* I, there is only one Profile I that results. (Rule 132 of Thomas G. Rehberger, ¶5). The legibility of Figure 1 is addressed by providing replacement figures. Replacement Figure 1A is a digital image of original photograph shown in Figure 1. (*Id.*, ¶3). Replacement Figure 1B was created by taking the digital image of Figure 1A and analyzing it with a software program (BioNumerics, Applied Maths, Belgium) used for analysis of DNA banding patterns.

The software program marks each band on the gel with a mark which collectively is the fingerprint for each enzyme used in the pulse field electrophoresis gel of Figure 1A. (*Id.*, ¶3).

A person having ordinary skill in the art to which the invention pertains would understand that amended claim 19 of the above-referenced application, which refers to Figure 1A, Figure 1B, and Table 6 are not vague, indefinite, and confusing in the recitation of "that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure 1A, Figure 1B, and Table 6," especially in light of the vastly improved replacement figures submitted herewith. (*Id.*, ¶4).

Table 6 shows strains that were digested with *Apa* I, *Not* I and *Xba* I, including all of the strains shown in Figures 1A-1B. The first 12 strains listed in Table 6 have a Profile I profile. The remaining strains of Table 6 have a Profile II, III, IV, V, VI, or VII profile. One of the specific properties of the claimed strains is having a Profile I profile (as shown in Figures 1A-1B) when digested with *Apa* I, *Not* I and *Xba* I. Table 6 shows that the first two strains of the gel shown in Figures 1A-1B, i.e., strains 1E-1 and 1D-3, have a Profile I profile when so digested. Lastly, in Table 6, the term "representative pigs" was used because it was a subset of the pigs that were examined. (*Id.*, ¶6).

Claim 26 is rejected due to the recitation of "milk replacer." This rejection is respectfully traversed because this term is well understood by those skilled in the art. As the MPEP points out, the essential inquiry pertaining to the definiteness requirement is

whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent.

MPEP §2173.02 (emphasis added).

Evidence that milk replacer is well known by those skilled in the art can be found in the list of 162 U.S. patents, each of which uses milk replacer, and of which twenty-five use this term in the claims (attached as Exhibit A). These patents include U.S. Patent No. 5,795,602, which is cited against claims 19-35 of the instant application. Thus, milk replacer complies with the

definiteness requirement.

The Office Action contends that “claims 23 and 34 respectively 24 and 35 appear to be substantial duplicates.” However, claims 23 and 24 depend from independent claim 19, whereas claims 34 and 35 depend from independent claim 30, which differs from claim 19. Thus, the claims are not duplicative.

The remaining claims specifically listed under this rejection have been addressed per the Examiner’s suggestion. The Examiner is thanked for her careful review of the claims.

In light of the amendments and the foregoing arguments, withdrawal of this rejection is requested.

3. Rejection Under §112, First Paragraph (Enablement)

Claims 19-35 stand rejected under 35 U.S.C. §112, ¶1 as being not enabled because deposit of strain 1E-1 is not mentioned.

Applicants believe that, in light of the written description, a deposit is not required to meet the enablement requirement. Applicants, however, have satisfied the criteria of 37C.F.R. §§ 1.801-1.809 through the amendment and statement described below, simply to clarify the location and nature of the deposit and not as an admission that the deposit is required under 35 U.S.C. § 112.

Specifically, the specification has been amended so that it identifies the deposit by accession number, date of deposit, and name and address of the depository.

In addition, attached as Exhibit B is a Rule 132 Declaration of Dr. Thomas G. Rehberger, a co-inventor and Vice President of the assignee, declaring that strain 1E-1 has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure (Budapest Treaty) and that, subject to 37 C.F.R. § 1.808(b), all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon granting of the patent.

Also attached as Exhibit C is a copy of the deposit receipt, evidencing the above-described deposit under the Budapest Treaty.

Furthermore, a Statement under MPEP § 2406.02 is attached as Exhibit D because the original deposit was made after the effective filing date of the application for patent.

Claims 22 and 33 have been amended to include the ATCC Accession Number of

Lactobacillus brevis strain 1E-1.

In light of the above-described declaration, statement, and amendment, withdrawal of the rejection is requested.

4. Rejections Based on the Prior Art

Claims 19-35 stand rejected under § 102(b) as being anticipated by and/or unpatentable over Tannock et al., Krause et al., Benoit et al., Coventry et al., Schutz, Lewus et al., Craig et al. (U.S. Patent No. 5,795,602), and Iritani et al. (U.S. Patent No. 6,090,416), either alone or in combination. The Applicants respectfully traverse this rejection because, as is discussed below, the references, alone or in combination, do not disclose each and every element of the claimed invention, nor do they teach or suggest the claimed invention. Therefore, reconsideration is in order and is respectfully requested.

a. Tannock et al.

Claims 19-28 and 30-35 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tannock et al. The Examiner suggests that Tannock et al. discloses at least one *Lactobacillus* strain that has a Profile I which has been optionally isolated from a pig. The Examiner notes that the strains are identified as *L. fermentum*. However, although the *L. fermentum* strains of Tannock et al. are isolated from a pig, none of the strains has a Profile I, as claims 19 and 30 require.

As is summarized in Table 6 of the specification, seven different profiles were identified in the *Lactobacillus* strains isolated by the inventors. Furthermore, some of the *Lactobacillus* strains of Table 6 having a Profile I are not *L. brevis*. Instead, they are *L. fermentum* and *L. murinus*. In addition, in Table 6, some of the *L. brevis* have different profiles, including I, II, and IV. Thus, just because a strain is a specific *Lactobacillus* species, does not mean that it will have a specific profile. Also, just because a *Lactobacillus* strain has a specific profile, does not mean that it will be a specific species. Hence, although Tannock et al. shows several *Lactobacillus* strains, including *L. fermentum* and *L. brevis* strains, Tannock et al. fails to disclose at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure 1 and Table 6, as claims 19 and 30 require.

In addition, the Examiner's factual assertion that Tannock et al. discloses at least one *Lactobacillus* strain that has a Profile I which has been optionally isolated from a pig is not considered to be common knowledge or well-known in the art because the applicants found multiple profiles in strains isolated from the GI tract of pigs. Therefore, the applicants demand that the Examiner produce authority for her statement. MPEP § 2144.03 C; In re Chevenard, 139 F.2d 711, 713, 60 USPQ 239, 241 (CCPA 1943). Alternatively, if the Examiner is relying on personal knowledge to support the finding of what is known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. MPEP § 2144.03 C.

Dependent claims 20-28 and 31-35 are believed to be in condition for allowance for incorporating by reference the limitations of claims 19 and 30, respectively, and for defining additional features of the invention, which, when considered in combination with those of their base claims, are neither disclosed nor suggested by the prior art relied upon in the rejection.

For example, claims 20 and 32 require the *Lactobacillus* strain to decrease levels of coliforms within the gastrointestinal tract of an animal. Claims 22 and 33 require the strain to be *L. brevis* strain 1E-1. None of these additional requirements are found in Tannock et al. Thus, for these additional reasons, claims 20, 22, 32, and 33 are not anticipated by Tannock et al.

In sum, Tannock et al. fails to anticipate the claimed invention. Withdrawal of the rejection based on this reference is therefore requested.

b. Krause et al.

Claims 19-28 and 30-35 are rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Krause et al. The Examiner suggests that the cited reference discloses at least one *Lactobacillus* strain that appears to be identical to the presently claimed strain since it is presumed to have Profile I based on the *Apa* I, *Not* I and *Xba* I digests because it has been isolated from the gastrointestinal tract (GI) tract of a pig. However, the Krause et al. reference cannot be presumed to have the required profile for this reason because as is noted above, the *Lactobacillus* strains of Table 6, which were isolated from the GI tract of a pig, can have different profiles.

In addition, the Examiner's factual assertion that the cited reference discloses at least one *Lactobacillus* strain that appears to be identical to the presently claimed strain since it is

presumed to have Profile I based on the *Apa* I, *Not* I and *Xba* I digests because it has been isolated from the gastrointestinal tract (GI) tract of a pig is not considered to be common knowledge or well-known in the art because the applicants found multiple profiles in strains isolated from the GI tract of pigs. Therefore, the applicants demand that the Examiner produce authority for her statement. MPEP § 2144.03 C; In re Chevenard, 139 F.2d 711, 713, 60 USPQ 239, 241 (CCPA 1943). Alternatively, if the Examiner is relying on personal knowledge to support the finding of what is known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. MPEP § 2144.03 C.

In sum, the Krause et al. reference does not anticipate claims 19 and 30, which require at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure 1 and Table 6.

Furthermore, claims 19 and 30 are not unpatentable in view of the Krause et al. reference. The Examiner suggests that

even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share.

(page 6 of Office Action (emphasis added)).

The Applicants believe that the Examiner has failed to make a *prima facie* case of obviousness, and, more particularly, has failed to establish the inherency of undisclosed properties. Specifically, to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03 (citing to In re Royka, 180 USPQ 580 (CCPA 1974)). Here, the microorganism recited in the claims is distinguishable from the cited reference based on identified characteristics, i.e., having a specific profile based on the restriction enzyme digests listed in claims 19 and 30. Thus, all the claim limitations are not taught or suggested by the prior art, and this reference would not have made obvious claims 19 and 30, nor the claims that depend therefrom.

Furthermore, with respect to inherency, the Examiner has failed to show that the undisclosed elements must be present in the prior art reference. Inherency of an undisclosed

element can only be established by showing that the inherency is necessary and inevitable and not merely possible or even probable. Interchemical Corp. v. Watson, 111 USPQ 78, 79(d) (D.C. 1956), *aff'd*, 116 USPQ 119 (D.C. Cir. 1958); MPEP §2112. In addition, inherency and obviousness are distinct concepts. W.L. Gore & Assoc. v. Garlock, Inc., 220 USPQ 303, 314 (Fed. Cir. 1983). In order to establish a *prima facie* case of obviousness based on inherent properties, the Examiner must show that the undisclosed properties are not only inevitably and necessarily present, but also that the inherency of the undisclosed properties or elements is obvious to one skilled in the art. Kloster Speedsteel AB v. Crucible Inc., 230 USPQ 81, 88 (Fed. Cir. 1986). Moreover, the Examiner has failed to show that any undisclosed properties are not only inevitably and necessarily present, but also that the inherency of the undisclosed properties or elements is obvious to one skilled in the art. Accordingly, Krause et al. would not have made claims 19 and 30 obvious.

Dependent claims 20-28 and 31-35 are believed to be in condition for allowance for incorporating by reference the limitations of claims 19 and 30, respectively, and for defining additional features of the invention, which, when considered in combination with those of their base claims, are neither disclosed nor suggested by the prior art relied upon in the rejection.

For example, claims 20 and 32 require the *Lactobacillus* strain to decrease levels of coliforms within the gastrointestinal tract of an animal. Claims 22 and 33 require the strain to be *L. brevis* strain 1E-1. None of these additional requirements are found in Krause et al. Thus, for these additional reasons, claims 20, 22, 32, and 33 are not anticipated by, nor would have been obvious over, Krause et al.

Accordingly, withdrawal of the rejections based on this reference is therefore requested.

c. Benoit et al.

Claims 19-28 and 30-35 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Benoit et al. Again, the Examiner suggests that it is appropriate to presume that the strains disclosed in this reference have the same Profile as those required by the claims because they have been isolated from a pig. However, this is not the case as is noted above.

In addition, the Examiner's factual assertion that it is appropriate to presume that the strains disclosed in this reference have the same Profile as those required by the claims because

they have been isolated from a pig is not considered to be common knowledge or well-known in the art because the applicants found multiple profiles in strains isolated from the GI tract of pigs. Therefore, the applicants demand that the Examiner produce authority for her statement. MPEP § 2144.03 C; In re Chevenard, 139 F.2d 711, 713, 60 USPQ 239, 241 (CCPA 1943).

Alternatively, if the Examiner is relying on personal knowledge to support the finding of what is known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. MPEP § 2144.03 C.

Thus, Benoit et al. does not teach each and every element of claims 19 and 30.

The Examiner also suggests that the claims would have been obvious over the cited reference, using the same line of reasoning as was used with the Krause et al. reference. However, because the microorganism recited in the claims 19 and 30 is distinguishable from the cited reference based on identified characteristics, a *prima facie* case of obviousness has not been established. Moreover, the Examiner has failed to show that any undisclosed properties are not only inevitably and necessarily present, but also that the inherency of the undisclosed properties or elements is obvious to one skilled in the art. Thus, Benoit et al. would not have made claims 19 and 30 obvious.

Dependent claims 20-28 and 31-35 are believed to be in condition for allowance for incorporating by reference the limitations of claims 19 and 30, respectively, and for defining additional features of the invention, which, when considered in combination with those of their base claims, are neither disclosed nor suggested by the prior art relied upon in the rejection.

For example, dependent claims 20 and 32 require that the strain decreases levels of coliforms within the gastrointestinal tract of an animal. Table 1 of the Benoit et al. reference shows that the strain described therein did not inhibit *E. coli*, which is a coliform. Thus, for this additional reason, Benoit et al. does not anticipate nor does it render obvious the claims 20 and 32.

In addition, claims 22 and 33 require the strain to be *L. brevis* 1E-1. Benoit et al. clearly fails to show, teach or suggest this additional requirement.

Accordingly, Benoit et al. fails to anticipate the claimed invention, nor would it have made the claimed invention obvious. Withdrawal of the rejections based on this reference is therefore requested.

d. Coventry et al.

Claims 19-28 and 30-35 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Coventry et al. The Examiner suggests that the reference discloses at least one *Lactobacillus* strain that appears to be identical to the presently claimed strain since it is presumed to have the required profile of the claim because it has been isolated from a pig. Applicants respectfully note that this is not the case because the strain is said to be isolated from a vacuum-packaged meat, the origin of which is not disclosed. Furthermore, even if the *Lactobacillus* strains were isolated from a pig, as is noted above, this does not mean that the strains would have a Profile I as is required by the claims. As such, the Coventry et al. reference does not anticipate claims 19 and 30.

In addition, the Examiner's factual assertion that the reference discloses at least one *Lactobacillus* strain that appears to be identical to the presently claimed strain since it is presumed to have the required profile of the claim because it has been isolated from a pig is not considered to be common knowledge or well-known in the art because the applicants found multiple profiles in strains isolated from the GI tract of pigs. Therefore, the applicants demand that the Examiner produce authority for her statement. MPEP § 2144.03 C; In re Chevenard, 139 F.2d 711, 713, 60 USPQ 239, 241 (CCPA 1943). Alternatively, if the Examiner is relying on personal knowledge to support the finding of what is known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. MPEP § 2144.03 C.

The Examiner also suggests that the claims would have been obvious over the cited reference, using the same line of reasoning as was used with the Krause et al. reference. However, because the microorganism recited in the claims 19 and 30 is distinguishable from the cited reference based on identified characteristics, a *prima facie* case of obviousness has not been established. Moreover, the Examiner has failed to show that any undisclosed properties are not only inevitably and necessarily present, but also that the inherency of the undisclosed properties or elements is obvious to one skilled in the art.

Dependent claims 20-28 and 31-35 are believed to be in condition for allowance for incorporating by reference the limitations of claims 19 and 30, respectively, and for defining additional features of the invention, which, when considered in combination with those of their base claims, are neither disclosed nor suggested by the prior art relied upon in the rejection.

For example, the *Lactobacillus* strain of Coventry et al. is not active against coliforms as claims 20 and 32 require. Instead, it is only shown to be active against *Listeria monocytogenes*. Thus, claims 20 and 32 are not satisfied for this additional reason.

In addition, claims 22 and 33 require the strain to be *L. brevis* 1E-1. Coventry et al. clearly fails to show, teach or suggest this additional requirement.

Accordingly, the claimed invention would not have been obvious over the Coventry et al. reference. Withdrawal of the rejections based on this reference is therefore requested.

e. Schutz et al.

Claims 19-28 and 30-35 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative 35 U.S.C. § 103(a) as obvious over Schutz et al. The Examiner suggests that because at least one *Lactobacillus* strain of Schutz belongs to the same species as the claimed invention, it is considered to anticipate the claimed microorganism. However, as is noted above, the same species can have different DNA profiles. As such, the Schutz et al. reference does not anticipate these claims.

In addition, the Examiner's factual assertion that because at least one *Lactobacillus* strain of Schutz belongs to the same species as the claimed invention, it is considered to anticipate the claimed microorganism is not considered to be common knowledge or well-known in the art because the applicants found multiple profiles in strains isolated from the GI tract of pigs. Therefore, the applicants demand that the Examiner produce authority for her statement. MPEP § 2144.03 C; In re Chevenard, 139 F.2d 711, 713, 60 USPQ 239, 241 (CCPA 1943). Alternatively, if the Examiner is relying on personal knowledge to support the finding of what is known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. MPEP § 2144.03 C.

The Examiner also suggests that the claims would have been obvious over the cited reference, using the same line of reasoning as was used with the Krause et al. reference. However, because the microorganism recited in the claims 19 and 30 is distinguishable from the cited reference based on identified characteristics, a *prima facie* case of obviousness has not been established. Moreover, the Examiner has failed to show that any undisclosed properties are not only inevitably and necessarily present, but also that the inherency of the undisclosed properties or elements is obvious to one skilled in the art.

Dependent claims 20-28 and 31-35 are believed to be in condition for allowance for incorporating by reference the limitations of claims 19 and 30, respectively, and for defining additional features of the invention, which, when considered in combination with those of their base claims, are neither disclosed nor suggested by the prior art relied upon in the rejection.

For example, the *Lactobacillus* strain of Schutz et al. is not active against coliforms as claims 20 and 32 require. Thus, claims 20 and 32 are not satisfied for this additional reason.

In addition, claims 22 and 33 require the strain to be *L. brevis* 1E-1. Schutz et al. clearly fails to show, teach or suggest this additional requirement.

Accordingly, the claimed invention would not have been obvious over the Schutz et al. reference. Withdrawal of the rejections based on this reference is therefore requested.

f. Lewus et al.

Claims 19-28 and 30-35 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative 35 U.S.C. § 103(a) as obvious over Lewus et al. The Examiner suggests that because the *Lactobacillus* strain described in Lewus et al. belongs to the same species as the claimed invention, it anticipates the claimed microorganisms. However, as is noted above, just because the strain might be the same species does not mean that it would have the same DNA profile as is required by the claim. Because Lewus et al. fails to disclose a *Lactobacillus* strain having a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure 1 and Table 6, as claims 19 and 30 require, this reference fails to anticipate these claims.

In addition, the Examiner's factual assertion that because the *Lactobacillus* strain described in Lewus et al. belongs to the same species as the claimed invention, it anticipates the claimed microorganisms is not considered to be common knowledge or well-known in the art because the applicants found multiple profiles in strains isolated from the GI tract of pigs. Therefore, the applicants demand that the Examiner produce authority for her statement. MPEP § 2144.03 C; In re Chevenard, 139 F.2d 711, 713, 60 USPQ 239, 241 (CCPA 1943). Alternatively, if the Examiner is relying on personal knowledge to support the finding of what is known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. MPEP § 2144.03 C.

The Examiner also suggests that the claims would have been obvious over the cited reference, using the same line of reasoning as was used with the Krause et al. reference.

However, because the microorganism recited in the claims 19 and 30 is distinguishable from the cited reference based on identified characteristics, a *prima facie* case of obviousness has not been established. Moreover, the Examiner has failed to show that any undisclosed properties are not only inevitably and necessarily present, but also that the inherency of the undisclosed properties or elements is obvious to one skilled in the art.

Dependent claims 20-28 and 31-35 are believed to be in condition for allowance for incorporating by reference the limitations of claims 19 and 30, respectively, and for defining additional features of the invention, which, when considered in combination with those of their base claims, are neither disclosed nor suggested by the prior art relied upon in the rejection.

For example, the *Lactobacillus* strains of Lewus et al. are not active against coliforms as claims 20 and 32 require. Thus, claims 20 and 32 are not satisfied for this additional reason.

In addition, claims 22 and 33 require the strain to be *L. brevis* 1E-1. Lewus et al. clearly fails to show, teach or suggest this additional requirement.

Accordingly, the claimed invention would not have been obvious over the Lewus et al. reference. Withdrawal of the rejections based on this reference is therefore requested.

g. Combination of References

Claims 19-35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tannock et al. taken with Krause et al., Craig et al. (U.S. Patent No. 5,795,602) and Iritani et al. (U.S. Patent No. 6,090,416).

The shortcomings in the teachings of Tannock et al. and Krause et al. are discussed above. The Craig et al. patent is cited for its alleged teachings of the benefits of probiotics added to milk. The Iritani et al. reference is cited for alleged teaching that fermented compositions are provided in the form of gruel. However, the teachings of Craig et al. and Iritani et al. cannot cure the deficiencies in the teachings of Tannock et al. and Krause et al. That is, the references, alone or in combination, fail to teach or suggest a *Lactobacillus* strain having a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure 1 and Table 6, as is required by the claims. Therefore, a *prima facie* case of obviousness has not been made.

In light of the foregoing, withdrawal of the rejection of claims 19-35 is respectfully requested.

5. New Claims

New claims 40-44 have been added and are believed to be in condition for allowance.

No new matter has been added.

CONCLUSION

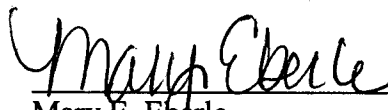
It is submitted that original claims 19-35 are in compliance with 35 U.S.C. §§ 112, 102, and 103 and each define patentable subject matter. New claims 40-44 are also believed to be allowable. A Notice of Allowance is therefore respectfully requested.

The Director is authorized to charge Deposit Account No. 23-2053 for the fee associated with a three-month extension, which the Applicants hereby request, and the fee associated with adding the new claims. No other fee is believed to be payable with this communication. Nevertheless, should the Examiner consider any other fees to be payable in conjunction with this or any future communication, the Director is authorized to direct payment of such fees, or credit any overpayment, to Deposit Account No. 23-2053.

The Examiner is invited to contact the undersigned by telephone if it would help expedite matters.

Dated this 8th day of January, 2007.

Respectfully submitted,



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EXHIBIT A

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"milk replacer"

PAT. NO.	Title
1 7,090,885	T Low isoflavones, high saponins soy protein product and process for producing the same
2 7,045,149	T Ruminal fluid inoculation of calves
3 6,967,090	T Nucleic acid and protein sequences of bovine epidermal growth factor
4 6,939,864	T Animal feed compositions and methods of using the same
5 6,939,216	T System and method for processing meat
6 6,923,957	T Salmonella vaccine materials and methods
7 6,921,535	T Attenuated Bovine Respiratory Syncytial virus
8 6,910,444	T Heated milk supply system for livestock
9 6,890,541	T Method for enhancing production performance in an animal
10 6,864,362	T Hypoallergenic transgenic soybeans
11 6,852,347	T Partially thermal treated dough intermediate and method of making
12 6,833,149	T Method and apparatus for processing vegetable oil miscella, method for conditioning a polymeric microfiltration membrane, membrane, and lecithin product
13 6,830,010	T Quality assurance program and method for meat production
14 6,811,798	T Method for manufacturing a soy protein product
15 6,803,068	T Highly soluble, high molecular weight soy protein
16 6,797,309	T Soy protein product and process for its manufacture
17 6,787,166	T Use of an acid preparation as feed additive in farm animal husbandry
18 6,787,151	T Composition for lowering blood cholesterol
19 6,777,396	T Feed for livestock
20 6,706,697	T Diabetic nutrition and weight loss drink compositions
21 6,693,104	T Theobromine with an anti-carcinogenic activity
22 6,677,500	T Ungulates expressing exogenous IGF-I in their milk
23 6,673,566	T Diagnosis of pathogen infections through analysis of nitrite production by antigen stimulated

leukocytes

- 24 [6,592,873](#) **T** [Polynucleic acids isolated from a porcine reproductive and respiratory syndrome virus \(PRRSV\) and proteins encoded by the polynucleic acids](#)
- 25 [6,589,583](#) **T** [Freezer to oven dough products](#)
- 26 [6,564,502](#) **T** [Process for using water-sensitive insecticides as an active ingredient in a water-based pest bait](#)
- 27 [6,541,047](#) **T** [Milk replacer and dry feed compositions and methods](#)
- 28 [6,485,902](#) **T** [Use of bacteriophages for control of escherichia coli O157](#)
- 29 [6,479,295](#) **T** [Method for determining fat \(crude\) in feed, food, and other materials utilizing filter media encapsulation](#)
- 30 [6,458,377](#) **T** [Wettable powder compositions of ionophore antibiotics](#)
- 31 [6,451,856](#) **T** [Carnitine supplemented diets for gestating and lactating swine](#)
- 32 [6,423,348](#) **T** [Anticoagulant compositions](#)
- 33 [6,406,729](#) **T** [Method and process for producing an improved milk replacer](#)
- 34 [6,365,174](#) **T** [Wettable powder compositions of ionophore antibiotics](#)
- 35 [6,365,152](#) **T** [Scours treatment and method of making same](#)
- 36 [6,348,223](#) **T** [Milk replacer composition and method](#)
- 37 [6,348,222](#) **T** [Milk replacer without animal fat, for feeding veal calves](#)
- 38 [6,299,912](#) **T** [Preparation for administration to animals and feeding method thereof](#)
- 39 [6,296,879](#) **T** [Ruminal fluid inoculation of calves](#)
- 40 [6,276,264](#) **T** [Portable batch pasteurizer](#)
- 41 [6,251,404](#) **T** [Method of producing a vaccine which raises an immunological response against a virus causing a porcine respiratory and reproductive disease](#)
- 42 [6,245,379](#) **T** [Method of administering a milk substitute to critical care animals](#)
- 43 [6,242,487](#) **T** [Carnitine supplemented diets for gestating and lactating swine](#)
- 44 [6,221,360](#) **T** [Infectious bovine rhinotracheitis vaccines and methods](#)
- 45 [6,183,739](#) **T** [Phospholipases in animal feed](#)
- 46 [6,176,916](#) **T** [Gluten lactose blends](#)
- 47 [6,156,333](#) **T** [Feed fortifier and enhancer for preruminant calves and method of using same](#)
- 48 [6,136,338](#) **T** [Oral veterinary composition containing a fluoroquinolone antibacterial agent possessing superior absorption properties and an extended duration of therapeutic antimicrobial blood levels, and a method of treating microbial infection in a ruminant](#)
- 49 [6,130,250](#) **T** [Veterinary use of a pleuromutilin derivative](#)
- 50 [6,110,467](#) **T** [Isolated porcine respiratory and reproductive virus, vaccines and methods of protecting a pig against a disease caused by a porcine respiratory and reproductive virus](#)

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'milk replacer': 162 patents.

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"milk replacer"

PAT. NO.	Title
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- | | | |
|----|---------------------------|---|
| 51 | 6,099,855 | T Therapeutic, production and immunostimulatory uses of biocidal compositions |
| 52 | 6,096,353 | T Calf milk replacer |
| 53 | 6,030,649 | T Process for treating pre-dried animal meal |
| 54 | 6,027,735 | T Products and processes for gastric cascade and gastrointestinal disorder treatment with same |
| 55 | 6,024,979 | T Oral veterinary composition containing a fluoroquinolone antibacterial agent possessing superior absorption properties and an extended duration of therapeutic antimicrobial blood levels, and a method of treating a microbial infection in a ruminant |
| 56 | 6,024,959 | T Pharmaceutical composition containing pectin and a phospholipid used as an antidiarrheal and antiulcer agent |
| 57 | 6,017,530 | T Phospholipases in animal feed |
| 58 | 5,965,128 | T Control of enterohemorrhagic E. coli 0157:H7 in cattle by probiotic bacteria and specific strains of E. coli |
| 59 | 5,962,254 | T Nitrogenous composition resulting from the hydrolysis of wheat gluten and process for its manufacture |
| 60 | 5,925,190 | T Production of fructose dianhydride products from inulin |
| 61 | 5,919,499 | T Aiding fermentation digestion and metabolism in mammals |
| 62 | 5,882,714 | T Queens milk replacer |
| 63 | 5,874,103 | T Ionophore antibiotic formulations |
| 64 | 5,858,449 | T Isoflavone-enriched soy protein product and method for its manufacture |
| 65 | 5,834,027 | T Injection of rhea and ostrich oils in animals |
| 66 | 5,797,505 | T Debris immune animal feeding nipple |
| 67 | 5,795,602 | T Milk enhancer and milk feed composition |

[T](#)

- 68 [5,792,501](#) [Queen's milk replacer](#)
- 69 [5,785,990](#) [Feed fortifier and enhancer for preruminant calves and method of using same](#)
- 70 [5,784,999](#) [Animal feeding nipple](#)
- 71 [5,756,136](#) [Controlled release encapsulation compositions](#)
- 72 [5,756,132](#) [Milk replacer for calves, and method](#)
- 73 [5,753,622](#) [Use of epidermal growth factor as a gastrointestinal therapeutic agent](#)
- 74 [5,753,283](#) [Method for stabilizing rice bran and rice bran products](#)
- 75 [5,725,861](#) [Products and processes for gastric cascade and gastrointestinal disorder treatment with same](#)
- 76 [5,719,121](#) [Use of balhimycin as production promoter in animals, and production promoter compositions](#)
- 77 [RE35,699](#) [Process to correct and optimize the composition of feed](#)
- 78 [5,695,766](#) [Highly virulent porcine reproductive and respiratory syndrome viruses which produce lesions in pigs and vaccines that protect pigs against said syndrome](#)
- 79 [5,662,922](#) [Iron-containing composition for the prevention of anaemia and a method for producing the composition](#)
- 80 [5,643,772](#) [Cryptosporidium hybrid vector and transformed host cells](#)
- 81 [5,641,759](#) [Animal husbandry methods and compositions therefor](#)
- 82 [5,589,186](#) [Feed composition for ruminant animals and method of feeding ruminant animals with the same](#)
- 83 [5,585,098](#) [Oral administration of chicken yolk immunoglobulins to lower somatic cell count in the milk of lactating ruminants](#)
- 84 [5,571,542](#) [Method of making an animal feed having a stable suspension of psyllium](#)
- 85 [5,565,225](#) [Process for enhancing the nutritional value of soy protein for the young animal](#)
- 86 [5,512,307](#) [Method for stabilizing rice bran and rice bran products](#)
- 87 [5,474,028](#) [Animal feeding nipple](#)
- 88 [5,397,589](#) [Preparation of calcium fortified powdered milk products with improved dispersibility](#)
- 89 [5,376,390](#) [Stabilizing rice bran and rice bran products](#)
- 90 [5,296,243](#) [Process to correct and optimize the composition of feed](#)
- 91 [5,296,221](#) [Lactobacillus johnsonii ferm bp-2680 lactic acid bacteria preparations using the same and a process of manufacturing the preparations](#)
- 92 [5,292,537](#) [Method for stabilizing rice bran and rice bran products](#)
- 93 [5,260,057](#) [Method and product for the treatment of gastric disease](#)
- 94 [5,200,418](#) [Cryptosporidiosis amelioration](#)
- 95 [5,198,213](#) [Method of disease treatment utilizing an immunologically whey fraction](#)
- 96 [5,139,803](#) [Method and liposome composition for the stabilization of oxidizable substances](#)
- 97 [5,115,764](#) [Milk supply system for livestock](#)
- 98 [5,100,679](#) [Method of making a modified proteinaceous product and composition thereof](#)
- 99 [5,082,674](#) [Food product](#)
- 100 [5,066,491](#) [Method of disease treatment utilizing an immunologically active whey fraction](#)
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PAT. NO.	Title
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- | | |
|---------------|--|
| 101 5,035,903 | T High fiber bakery products |
| 102 5,015,483 | T Liposome composition for the stabilization of oxidizable substances |
| 103 4,961,934 | T Milk replacer for infant cattle and method for breeding infant cattle using the same |
| 104 4,960,589 | T Method of enhancing growth and improving feed conversion ratio in animals and block for use therein |
| 105 4,948,782 | T A method of promoting the growth of domestic animals with erythromycin derivative containing composition |
| 106 4,944,944 | T Dietary compositions and methods using bile salt-activated lipase |
| 107 4,929,466 | T Food and feedstuff |
| 108 4,910,019 | T Oxathiadiazole growth promoters |
| 109 4,879,113 | T Vaccine for immunologically mediated nutritional disturbances associated with plant protein antigens |
| 110 4,871,574 | T Process for preparing flour from Jerusalem artichoke tubers |
| 111 4,869,907 | T Method of enhancing growth and weight gain in swine and block for use therein |
| 112 4,835,185 | T Immunomodulator for improving commercial performance of domestic animals |
| 113 4,810,518 | T Particulate creamer-thickener and process of preparing the same |
| 114 4,803,955 | T Milk calf feeding system with automatic cleaning cycle |
| 115 4,794,105 | T Method for treatment of swine dysentery |
| 116 4,760,090 | T Method of feeding ketoisocaproate to cattle and sheep |
| 117 4,760,055 | T Growth-stimulating animal feed, a process for preparing it, and an additive to be used in it |
| 118 4,757,784 | T Method and means for circulating fluid to livestock |
| 119 4,743,452 | T Method for producing frozen yeast-leavened dough |

- 120 4,701,445 [T Easily dispersible agglomerated hygroscopic compositions](#)
- 121 4,673,576 [T Method of producing veal and animal feed therefor](#)
- 122 4,652,448 [T Use of monoclonal antibodies against bacterial adhesins](#)
- 123 4,633,814 [T Floating calf feeder for feeding calves](#)
- 124 4,623,541 [T Production of purified porcine immunoglobulins](#)
- 125 4,617,190 [T Enzymatic powder milk](#)
- 126 4,614,653 [T Milk replacer and method of feeding](#)
- 127 4,600,585 [T Feeding regimen for minimizing weaning stress](#)
- 128 4,598,097 [T Pig feedstuff](#)
- 129 4,543,264 [T Method of treating oilseed material](#)
- 130 4,504,471 [T Animal growth promotant and method of use for animal growth](#)
- 131 4,500,548 [T Fermentation aid for conventional baked goods](#)
- 132 4,450,176 [T Method of treating soybean material](#)
- 133 4,443,549 [T Production of monoclonal antibodies against bacterial adhesins](#)
- 134 4,432,999 [T Whey-soybean product and process for making the product](#)
- 135 4,404,228 [T Lipid and protein containing material in particulate form and process therefor](#)
- 136 4,378,376 [T Simulated milk protein replacer of improved suspension characteristics](#)
- 137 4,341,808 [T Frozen raw custard](#)
- 138 4,323,584 [T Method of preparing animal feeds](#)
- 139 4,320,116 [T Foodstuffs, animal feeding stuffs and pharmaceutical preparations containing an antibacterial system](#)
- 140 4,294,856 [T Process for manufacture of artificial milk replacer for raising infant pigs and other infant animals](#)
- 141 4,291,053 [T Agent to be administered orally to domestic animals without cellulose digestion in the rumen](#)
- 142 4,283,435 [T Oxidized whey protein concentrate enriched shortening-containing biscuits](#)
- 143 4,279,939 [T Milk replacer for baking containing isolated vegetable protein](#)
- 144 4,269,864 [T Milk replacer for caramels](#)
- 145 4,265,925 [T Bland vegetable protein product and method of manufacture](#)
- 146 4,260,631 [T Oral administration of Salinomycin to pigs](#)
- 147 4,259,358 [T Preparation of food products](#)
- 148 4,239,783 [T Reduction of mixing time of yeast leavened dough compositions](#)
- 149 4,235,995 [T 3-Nitropyrazole derivatives](#)
- 150 4,214,009 [T Replacement of egg albumen in food compositions](#)
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PAT. NO. Title

- 151 [4,209,518](#) [Bicyclomycin as an animal growth promotant](#)
- 152 [4,207,346](#) [Process for making high density bread for use in a stuffing mix](#)
- 153 [4,192,887](#) [Ruminant coccidiostats](#)
- 154 [4,147,810](#) [Treatment of vegetable protein](#)
- 155 [4,145,554](#) [3-Nitropyrazole derivatives](#)
- 156 [4,112,123](#) [Nutritionally balanced single food composition and method of production](#)
- 157 [4,088,791](#) [Free flowing modified whey powder](#)
- 158 [4,081,555](#) [Preservation of whey](#)
- 159 [4,066,776](#) [Anti-bacterial compositions containing certain 3-nitropyrzoles](#)
- 160 [4,009,268](#) [Composition and method for reducing the incidence of scours in neo-natal ruminants](#)
- 161 [3,975,517](#) [Enteric disease vaccine](#)
- 162 [3,961,078](#) [Soluble waste conversion process and pasteurized proteinaceous products](#)

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aclm/"milk replacer"

PAT. NO. Title

- 1 [6,939,864](#)  [Animal feed compositions and methods of using the same](#)
- 2 [6,777,396](#)  [Feed for livestock](#)
- 3 [6,541,047](#)  [Milk replacer and dry feed compositions and methods](#)
- 4 [6,458,377](#)  [Wettable powder compositions of ionophore antibiotics](#)
- 5 [6,406,729](#)  [Method and process for producing an improved milk replacer](#)
- 6 [6,365,174](#)  [Wettable powder compositions of ionophore antibiotics](#)
- 7 [6,348,223](#)  [Milk replacer composition and method](#)
- 8 [6,348,222](#)  [Milk replacer without animal fat, for feeding veal calves](#)
- 9 [5,874,103](#)  [Ionophore antibiotic formulations](#)
- 10 [5,858,449](#)  [Isoflavone-enriched soy protein product and method for its manufacture](#)
- 11 [5,785,990](#)  [Feed fortifier and enhancer for preruminant calves and method of using same](#)
- 12 [5,756,132](#)  [Milk replacer for calves, and method](#)
- 13 [5,753,283](#)  [Method for stabilizing rice bran and rice bran products](#)
- 14 [5,512,307](#)  [Method for stabilizing rice bran and rice bran products](#)
- 15 [4,961,934](#)  [Milk replacer for infant cattle and method for breeding infant cattle using the same](#)
- 16 [4,810,518](#)  [Particulate creamer-thickener and process of preparing the same](#)
- 17 [4,623,541](#)  [Production of purified porcine immunoglobulins](#)
- 18 [4,614,653](#)  [Milk replacer and method of feeding](#)
- 19 [4,600,585](#)  [Feeding regimen for minimizing weaning stress](#)
- 20 [4,378,376](#)  [Simulated milk protein replacer of improved suspension characteristics](#)
- 21 [4,323,584](#)  [Method of preparing animal feeds](#)
- 22 [4,294,856](#)  [Process for manufacture of artificial milk replacer for raising infant pigs and other infant animals](#)
- 23 [4,279,939](#)  [Milk replacer for baking containing isolated vegetable protein](#)
- 24 [4,269,864](#)  [Milk replacer for caramels](#)
- 25 [4,081,555](#)  [Preservation of whey](#)

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EXHIBIT B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors:	Thomas G. Rehberger, et al.	Art Unit:	1651
Serial No.:	10/624,443	Examiner:	Irene Marx
Filed:	July 22, 2003	Confirmation No.:	6437
For:	Lactobacillus Strains and Uses Therefor		

RULE 132 DECLARATION OF THOMAS G. REHBERGER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, THOMAS G. REHBERGER, Ph.D., the undersigned Declarant, do hereby state and declare that:

1. I am a co-inventor of the invention described and claimed in the above-referenced patent application. I am the Vice President of Agtech Products, Inc., the assignee of the above-referenced patent application. I am a person having ordinary skill in the art to which the invention pertains.
2. Biological material (strain 1E-1) was deposited at the American Type Culture Collection (ATCC) under ATCC Accession No. PTA-6509 under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
3. Replacement Figure 1A is a digital image of original photograph shown in Figure 1. Figure 1B was created by taking the digital image of Figure 1A and analyzing it with a software program (BioNumerics, Applied Maths, Belgium) used for analysis of DNA banding patterns. The software program marks each band on the gel with a mark which collectively is the fingerprint for each enzyme used in the PFG.
4. A person having ordinary skill in the art to which the invention pertains would understand that amended claim 19 of the above-referenced application, which refers to Figure 1A, Figure 1B, and Table 6 are not vague, indefinite, and confusing in the recitation of "that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure 1A, Figure 1B, and Table 6," especially in light of the vastly improved replacement figures submitted herewith.

5. As it is currently understood, when digesting genomic DNA of strains of *Lactobacillus* with *Apa* I, *Not* I and *Xba* I, there is only one Profile I that results.
6. In Table 6, the term "representative pigs" was used because it was a subset of the pigs that were examined.
7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1002 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this Rule 132 Declaration is directed.

Dated: 1-08-07



Thomas G. Rehberger, Ph.D.

EXHIBIT C

ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.

To: (Name and Address of Depositor or Attorney)

Agtech Products, Inc.
Attn: Thomas Rehberger
Westmound Drive
Waukosha, WI 53186

Deposited on Behalf of: Agtech Products, Inc.

Identification Reference by Depositor:

Bacillus subtilis 3A-P4
Bacillus subtilis 15A-P4
Bacillus subtilis 22C-P1
Lactobacillus brevis 1E-1

Patent Deposit Designation

PTA-6506
PTA-6507
PTA-6508
PTA-6509

The deposits were accompanied by: a scientific description a proposed taxonomic description indicated above. The deposits were received January 12, 2005 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested January 19, 2005. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Marie Harris
Marie Harris, Patent Specialist, ATCC Patent Depository

Date: March 9, 2005

cc: Mary Eberle

Ref: Docket or Case No: 21169-2

EXHIBIT D

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: Thomas G. Rehberger et al.

Art Unit: 1651

Serial No. 10/624,443

Examiner: Irene Marx

Filed: July 22, 2003

Confirmation No.: 6437

For: *Lactobacillus* Strains and Uses Therefor

STATEMENT UNDER MPEP §2406.02

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The undersigned hereby states the following.

1. Biological material (strain 1E-1) was deposited at the American Type Culture Collection (ATCC) under ATCC Accession No. PTA-6509.
2. The biological material that was deposited under ATCC Accession No. PTA-6509 is biological material specifically identified in the application (the filing date of which is relied upon) as filed.
3. I am in a position to corroborate that the biological material which was deposited is a biological material specifically identified in the application (the filing date of which is relied upon) as filed because I personally made the deposit to the ATCC.



Marianne Bellot, Laboratory Manager